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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,072	07/14/2006	Douglas E. Brough	253625	7914
23460 7590 05/01/2007 LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			EXAMINER SHEN, WU CHENG WINSTON	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,072

Applicant(s)

BROUGH, DOUGLAS E.

Examiner

Wu-Cheng Winston Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-34 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-7 and 13-21, drawn to a method of changing the sensory perception of an animal, wherein the method comprises administering to the inner ear an expression vector comprising a nucleic acid sequence encoding an atonal-associated factor, wherein the nucleic acid sequence is expressed to produce the atonal-associated factor resulting in generation of sensory hair cells that allow perception of stimuli in the inner ear, wherein the expression vector is an *adeno-associated viral vector*.
- II. Claims 1-6 and 8-21, drawn to a method of changing the sensory perception of an animal, wherein the method comprises administering to the inner ear an expression vector comprising a nucleic acid sequence encoding an atonal-associated factor, wherein the nucleic acid sequence is expressed to produce the

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atonal-associated factor resulting in generation of sensory hair cells that allow perception of stimuli in the inner ear, wherein the expression vector is an *adenoviral vector*.

- III. Claims 22-34, drawn to a method of generating a hair cell in differentiated sensory epithelia *in vivo*, wherein the method comprises contacting differentiated sensory epithelial cells with an adenoviral vector (a) comprising an adenoviral genome deficient in one or more replication-essential gene functions of the E 1 region, the E4 region, and, optionally, the E3 region (b) comprising a spacer in the E4 region, and (c) comprising a nucleic acid sequence encoding an atonal-associated factor, wherein the nucleic acid sequence is expressed to produce the atonal-associated factor such that a hair cell is generated.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups, as stated in claims 1 and 22, is a nucleic acid sequence encoding an atonal-associated factor, including HATH 1 from human. However, this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art.

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Ben-Arie et al. teach nucleic acid sequence and expression of the bHLH (β helix-loop-helix) transcription factors, including HATH 1 from human (Ben-Arie et al. Evolutionary conservation of sequence and expression of the bHLH protein Atonal suggests a conserved role in neurogenesis. *Hum Mol Genet.* 5(9): 1207-16, 1996).

Inventions I-III are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different starting materials, different method steps, and/or different goals. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups I and II are related methods. Inventions of the Group I is patentably distinct from Group II because Group I is directed to a method of changing the sensory perception of an animal, wherein the method comprises administering to the inner ear an expression vector comprising a nucleic acid sequence encoding an atonal-associated factor, wherein the expression vector is an *adeno-associated viral vector* whereas Group II is directed a method of changing the sensory perception of an animal, wherein the method comprises administering to the inner ear an expression vector comprising a nucleic acid sequence encoding an atonal-associated factor, wherein the expression vector is an *adenoviral vector*. The nucleic acid sequences and intrinsic characteristics, including minimized immune response and cytotoxicity, of the adeno-associated

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viral vector of Group I are not obvious over the nucleic acid sequences and intrinsic characteristics, including cytotoxicity, of the adenoviral vector of Group II.

Groups I and II are patentably distinct from Group III because Groups I and II are directed to a method of changing the sensory perception of an animal whereas Group III is directed to a method of generating a hair cell in differentiated sensory epithelia *in vivo*. The steps and technical considerations of Groups I and II are not obvious over the steps and technical considerations of Group III.

The search of the above listed Groups I-III is distinct one from each other and not co-extensive and thereby presents search burdens on the examiner.

4. This application contains claims directed to the following patentably distinct species: a tumor growth factor, brain-derived neurotrophic factor, or nerve growth factor (claim 15). The species are independent or distinct because they are distinct neurotrophic agent with different amino acid residues and distinct structures and functions that modulate neuronal cell growth.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 15 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5 Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

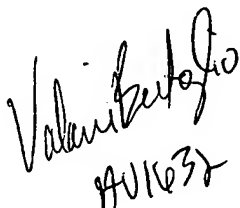
Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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